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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,696	12/05/2001	Daniel F. Bischof	F-5801	7252

7590 08/18/2004

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EXAMINER	
SAUCIER, SANDRA E	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 08/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM.

Office Action Summary	Application No.	Applicant(s)	
	10/004,696	BISCHOF ET AL.	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-10,25 and 28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-10,25 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-5, 7-10, 25, 28 are pending and are considered on the merits.

Claim Rejections - 35 USC § 112

INDEFINITE

Claims 1-5, 7-10, 25 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, last sentence on page 2 of the amended claims recites "of said blood". No blood is present in the process of claim 1, thus this recitation lacks a prior reference and cannot be "said blood".

Claim 4 is directed to plasma as the blood component. However, newly amended claim 1 requires that the blood component be centrifuged and form a supernatant and blood component layer. Plasma cannot easily be resolved into supernatant and blood component layer.

How do claims 9 and 10 now fit into the amended process of claim 1? They do not appear to make sense in the scheme as now presented.

Claim Rejections - 35 USC § 103

Claims 1-5, 7-10, 25 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,544,727 [IDS] or US 5,908742 [A].

The claims are directed to a method for preparing a blood product for pathogen inactivation comprising:
providing a container system with at least two containers, an interim container and a synthetic medium container, connected to each other,
providing a source container with a blood component,
connecting the source container to the interim container,
transferring the blood component to the interim container,

centrifuging to obtain a concentrate of the blood component by removing the supernatant,
combining the blood component with synthetic medium in the interim container.

The method is drawn in one embodiment to concentrating a platelet rich plasma (PRP) composition to form a platelet concentrate (PC) by centrifugation and expressing the plasma from the sedimented platelets, then substituting a synthetic medium for at least some of the plasma that was associated with the platelets in the PRP composition in preparation for a pathogen inactivation process. This process is performed using a two bag set comprising an empty bag and a bag containing synthetic medium.

US 6,544,727 and US 5,908,742 disclose forming a platelet concentrate (PC) from platelet rich plasma (PRP) composition by centrifugation to form a sedimented layer of platelets, removing some of the supernatant plasma, and adding a synthetic medium to the platelet concentrate in order to prepare the platelets for a pathogen inactivation method, See Figs 20A, 20B, 20C and Figs 9A, 9B, 9C respectively. Also, example 6 of '742. The process is performed in connected bag units.

The difference between the claimed method and the method disclosed in '727 or '742 is the manner in which the platelet concentrate is formed. In these references the bag which contains the platelet concentrate (PC) is attached to the donor set where the PC has been produced from PRP, and the PC bag is then detached from the donor set and attached to the set which includes the synthetic medium. In this set, PC has synthetic medium added to it in the desired amount prior to a viral inactivation process.

In contrast, the instant claims attach a platelet rich plasma (PRP) composition bag to a set which contains the synthetic medium and an

empty bag into which the PRP is transferred and centrifuged in order to produce the PC.

Whether one of skill in the art wishes to produce the platelet concentrate in a bag that is attached to the synthetic medium bag or in a bag that is attached to the donor set is within the purview of one of skill in the art, since sterile docking of blood bags is well known in the art and the results of both the claimed method and the disclosed method is the same, namely replacement of some of the plasma in a PRP with synthetic medium prior to pathogen inactivation. This does not appear to rise to the level of a patentable invention.

The substitution of red cells for platelets in the method of US 6,544,727 or US 5,908742 would have been obvious because '727 states in the "Summary of Invention" that the application provides method of using...compounds to inactivate pathogens ...particularly in blood products in synthetic media. Blood products include red cells. Thus, the suggestion to apply the methods disclosed in the examples is found in the generic disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sandra Saucier
Primary Examiner
Art Unit 1651